



## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2021-0728; FRL-10179-01-OMS]

### Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Section 8 of the Toxic Substances Control Act (TSCA)

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Section 8 of the Toxic Substances Control Act (TSCA) (EPA ICR Number 2703.01, OMB Control Number 2070-NEW) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a request to consolidate certain activities currently covered under other existing ICRs. Public comments were previously requested via the *Federal Register* on March 8, 2022, during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

**DATES:** Additional comments may be submitted on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** Submit your comments to EPA, referencing Docket ID No. EPA-HQ-OPPT-2021-0728, online using [www.regulations.gov](https://www.regulations.gov) (our preferred method), by email to <https://www.epa.gov/dockets>, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 2821T, 1200 Pennsylvania Ave., NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is

restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** Katherine Sleasman, Regulatory Support Branch (7602M), Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (202) 566-1204; email address: [sleasman.katherine@epa.gov](mailto:sleasman.katherine@epa.gov).

**SUPPLEMENTARY INFORMATION:** Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the docket for this ICR. The docket can be viewed online at [www.regulations.gov](http://www.regulations.gov) or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's dockets, visit <https://www.epa.gov/dockets>.

*Abstract:* This new ICR consolidates information collection activities established under TSCA section 8 currently approved by OMB under Control numbers: 2070-0004; 2070-0017; 2070-0054; and 2070-0067. Although imposed for a specific chemical substance, the activities are already established and only vary based on the specific authority under TSCA section 8 and the need for the information for that chemical. EPA is consolidating the existing ICRs to streamline the presentation of paperwork burden estimates, thereby reducing the administrative burden for both the public and the Agency and allowing a better assessment of the burden and costs for reporting and recordkeeping activities under TSCA section 8.

This ICR covers reporting and recordkeeping requirements in TSCA section 8, for persons who manufacture, import, or process chemical substances, mixtures, or categories, or distribute them in commerce. The purpose of the ICR activities is to collect data that will help

EPA evaluate the potential for human health and environmental risks caused by the manufacture, processing, and distribution in commerce of chemical substances, mixtures, or categories.

Under TSCA section 8(a), persons who manufacture, import, or process certain chemical substances or mixtures, or propose to manufacture, import, or process certain chemical substances or mixtures, are required to comply with the Preliminary Assessment Information Rule (PAIR) -- which requires manufacturers and importers of certain chemical substances to submit information about production, use, and/or exposure-related data -- and also potentially chemical-specific “8(a) rules” requiring additional, more detailed, information.

Under TSCA section 8(c), persons who manufacture, import, process, or distribute in commerce any chemical substance or mixture must keep records of significant adverse reactions to health or the environment, as determined by the Administrator by rule. Allegations of adverse reactions to the health of employees be kept for thirty years, and all other allegations be kept for five years. The rule also prescribes the conditions under which a firm must submit or make the records available to a duly designated representative of the Administrator.

Finally, under TSCA section 8(d), persons, who manufacture, import, process, or distribute in commerce (or propose to manufacture, import, process, or distribute in commerce) certain chemical substances and mixtures, are required to submit to EPA lists and copies of health and safety studies which relate to health and/or environmental effects of the chemical substances and mixtures. To comply with an “8(d)” rule, respondents must search their records to identify any health and safety studies in their possession, make copies of relevant studies, list studies that are currently in progress, and submit this information to EPA.

*Form Numbers:* 7710-51; 7710-35

*Respondents/Affected entities:* Manufacturers (including imports) or processors of chemical substances of mixtures, NAICS Codes 325 & 324.

*Respondent’s obligation to respond:* Mandatory (TSCA Section 8 and 40 CFR 704; 712; 716; 717; & 766)

*Estimated number of respondents:* 13,294 (total).

*Frequency of response:* On occasion.

*Total estimated burden:* 26,226 hours (per year). Burden is defined at 5 CFR 1320.3(b).

*Total estimated cost:* \$5,109,515 (per year), includes \$0 annualized capital or operation & maintenance costs.

*Changes in the estimates:* This information collection combines the burdens from four previously approved ICRs. The total burden hours requested for this ICR is 26,226 and the total estimated cost is \$5,109,515. There was an increase in the estimated number of responses for Section 8(d) Health and Safety Studies and Chemical Specific Section 8(a) because of the reinstatement of this ICR, and increased number of potential Section 8(d) submissions. The increase for these two information collections is 50 responses, 7 for Section 8(d) Health and Safety Studies and 43 Chemical Specific Section 8(a) respectively, from the two previously approved ICRs. The total combined cost burden from the Section 8(d) Health and Safety Studies and the Chemical Specific Section 8(a) currently approved ICRs is \$23,501 (\$23,501 + \$0), respectively, and the total cost burden requested for these information collections is ICR is \$56,397 (\$41,607 + \$14,790).

**Courtney Kerwin,**

*Director, Regulatory Support Division*

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